Docket No. CRD5046USANP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Donald K. Jones	Confirmation No.:	8210
Appln. No.	:	10/738,477	Art Unit :	3767
Filed	:	December 17, 2003	Examiner :	Osinski, Bradley James
Title	:	Activatable Bioactive Implantable Medical Device And Method Of Use		

CERTIFICATE OF TRANSMISSION			
I hereby certify that this correspondence is being electronically filed via EFS-Web to the Commissioner for Patents with the U.S. Patent and Trademark Office on: 4 June 2010			
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is filed in response to the Notice of Appeal, which was mailed by Appellant to the U.S. Patent & Trademark Office on March 12, 2010, which was filed in response to the Final Office Action of January 12, 2010.

Real Party In Interest:

By virtue of an assignment recorded at reel/frame 023032/0233, the real party in interest for this patent application is Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham 0276, which is wholly owned by Johnson & Johnson, a New Jersey corporation.

Related Appeals and Interferences:

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims:

Claims 1-16 have been withdrawn.

Claims 17 and 18 are pending, have been finally rejected, and are hereby appealed.

Status of Amendments:

No amendments have been filed after the final rejection of January 12, 2010.

Summary of Claimed Subject Matter:

Independent Claim 17

The present invention, as exemplified by independent claim 17, is directed to a method of treatment comprising the steps of:

providing a medical device comprising an embolic support member 10, a bioactive agent 20 disposed on the support member 10, and outer barrier 22 exhibiting the characteristic of normally preventing a reaction between the bioactive agent 20 and a bodily fluid; (See, *e.g.,* page 7, lines 16-18, Figure 2)

exposing a portion of the bioactive agent 20 when an external agent is applied to the barrier; (See, *e.g.,* page 8, lines 9-12)

inserting a delivery catheter 24 into a blood vessel; (See, *e.g.,* page 9, line 2, Figure 3A)

advancing the distal tip of delivery catheter 24 through the blood vessel until the distal tip is adjacent to a selected site within the blood vessel; (See, *e.g.,* page 9, lines 2-5, Figure 3A)

delivering the medical device with the delivery catheter 24 at the selected site; (See, *e.g.,* page 9, line 2, Figure 3A) and,

applying the external agent through the catheter and into the blood vessel to thereby dissolve the barrier to expose the bioactive agent 20 to bodily tissue to thereby cause a reaction between bioactive agent 20 and the bodily tissue. (See, *e.g.,* page 10, lines 14-16)

Independent Claim 18

The present invention, as exemplified by independent claim 18 is directed to a method of treatment comprising the steps of:

providing a medical device comprising an embolic support member 10 having a bioactive surface which reacts with bodily tissue, and having a barrier which exhibits the characteristic of normally inhibiting a reaction between the bioactive surface of the medical device and bodily tissue; (See, *e.g.,* page 9, lines 18-19)

inserting a delivery catheter 24 into a blood vessel; (See, *e.g.,* page 9, line 2, Figure 3A)

advancing the distal tip of delivery catheter 24 through the blood vessel until the distal tip is adjacent a selected site within the blood vessel; (See, *e.g.,* page 9, lines 2-5, Figure 3A)

delivering the medical device with delivery catheter 24 at the selected site; (See, *e.g.,* page 9, line 2, Figure 3A) and,

applying the external agent through the catheter to a selected site to thereby dissolve barrier and thus expose the bioactive surface to bodily tissue to thereby cause a

reaction between the bioactive surface and the bodily tissue. (See, *e.g.,* page 10, lines 14-16)

Grounds of Rejection To Be Reviewed On Appeal:

A) Whether the final rejection stating that claims 17 and 18 are unpatentable under 35 U.S.C. 103(a) should be reversed.

Argument:

Rejection of claims 17 and 18 under 35 USC 103(a)

The Examiner has finally rejected Claims 17-18 under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (US 2002/0143348) in view of Pinchuk et al (US 2002/0107330).

Appellant's respectfully submit that the cited references fail to teach or suggest the present invention, as recited in the claims. For example claims 17 and 18 include the following limitations, among others:

> a *barrier* exhibiting the characteristic of *normally preventing a reaction between the bioactive agent and a bodily fluid* and of *exposing* a portion of said bioactive agent *when an external agent is applied to said barrier;*
>
> * * *
>
> applying said *external agent* through the catheter and into the blood vessel *to thereby dissolve said barrier to expose said*

> *bioactive agent to bodily tissue* to thereby cause a reaction between the bioactive agent and the bodily tissue;

(Application, claim 17. Emphasis added)

> a *barrier* which exhibits the characteristic of normally *inhibiting a reaction between said bioactive surface of said medical device and bodily tissue*;
>
> * * *
>
> applying said *external agent* through the catheter to a selected *site to thereby dissolve said barrier and thus expose said bioactive surface to bodily tissue* to thereby cause a reaction between the bioactive agent and the bodily tissue;

(Application, claim 18. Emphasis added.)

For example, the Wallace reference describes "embolic assemblies that can be *reinforced in situ.*" (Abstract. Emphasis added.) The Wallace reference describes occlusive compositions.

> In one aspect, the invention includes a vaso-occlusive assembly, comprising (a) an implantable device having an axial lumen and (b) a liquid agent, wherein the liquid agent is infused into the lumen of the implantable device, and further wherein the liquid agent (i) self-polymerizes into a rigid or semi-rigid state after infusion (e.g., over a period of minutes to hours) or (ii) polymerizes upon interaction with one or more additional agents disposed in the lumen of the implantable device.

(Wallace, paragraph 13. Emphasis added.)

> This aspect of the Wallace reference is opposite to the present invention, in that the "liquid agent" polymerizes or self-polymerizes "into a rigid or semi-rigid state". In another aspect, the invention includes a vaso-occlusive assembly, comprising (a) an implantable device comprising a polymeric material and (b) a liquid agent capable of at least partially solvating the polymeric material of the implantable device.

(Wallace, paragraph 15. Emphasis added.)

> In embodiments in which the liquid agent comprises a solvating agent, the methods can serve to fuse the implantable device to itself or to one or more additional devices upon re-solidification of the solvated polymeric material.

(Wallace, paragraph 18. Emphasis added.)

The Wallace reference does mention "partially solvating polymeric materials of the implantable device," but describes that they will later "re-solidify":

> The liquid agent is capable of *transforming into a solid form* for example, slowly over time or by reaction with an agent already present in the luminal portion of the device. In addition, assemblies and methods are described comprising an implantable device and a liquid agent, wherein the liquid agent is capable of solvating polymeric material of the device. *By partially solvating polymeric materials of the implantable device, when these polymeric materials re-solidify* the implantable devices can be bonded to themselves and/or to other implantable devices.

(Wallace, paragraph 23. Emphasis added.)

> …the implantable device comprises a polymeric material capable of controllable being *at least partially solvated (or plasticized) and, subsequently, re-solidifying*. In these embodiments, the liquid agent comprises a substance that acts to at least partially solvate (or dissolve) the implantable device such that the device can then be bonded to itself (e.g., the individual winds of a coil) or bonded to another implantable device which has been similarly solvated.

(Wallace, paragraph 40. Emphasis added.)

The Examiner concedes that "Wallace does not, however specifically teach a bioactive agent disposed between the support member and the barrier nor does he teach the polymer is specifically a barrier." Appellant's agree completely.

Regarding the Pinchuk et al. reference, the Examiner states that it "does teach a barrier layer of polymers", and quotes Pinchuk:

> In some instances, it may be desirable to temporarily enclose the therapeutic-agent-loaded copolymer to prevent release before the medical device reaches its ultimate placement site.

(Pinchuk, paragraph 183.)

> It also may be useful to coat the copolymer of the present invention (which may or may not contain a therapeutic agent) with a layer with an additional polymer layer (which may or may not contain a therapeutic agent). This layer may serve, for example, as a boundary layer to retard diffusion of the therapeutic agent and prevent a burst phenomenon whereby

> much of the agent is released immediately upon exposure of the device or device portion to the implant site.

(Pinchuk, paragraph 204.)

One of the differences is that the barrier of the present invention does not release the bioactive agent until the external agent is applied. In other words, the prior art includes embolic devices having an outer coating which automatically dissolves when in contact with blood flow, without waiting for a specific external agent. As described in the "Description of the Prior Art" from the present application:\

> In addition, U.S. patent No. 5980,550, entitled, "Water-Soluble Coating For Bioactive Vasoocclusive Devices," discloses an embolic coil having an inner coating which serves as a thrombogenic agent and an *outer coating of a water soluble agent which dissolves after placement of the coil in order expose the thrombogenic inner coating* to enhance the growth of thrombus into an around the coil.
>
> *The water soluble collating prevents the thrombogenic inner coating from coming into contact with the surrounding blood until the water soluble coating is dissolved by contact with blood which is comprised largely of water*.
>
> While the vasculature occlusive device disclosed in this patent includes an agent for enhancing thrombogenicity of the device and also includes an outer coating to prevent such activity until the outer coating is dissolved by blood flow, *there is no control over when the dissolving process begins* and therefore *no control over the time in which the thrombogenic agent becomes activated*. Without such control, it is possible that thrombus can begin forming on the coil prior to the time the coil is properly placed within a vessel, or aneurysm, therefore making it very difficult if not impossible to reposition, or remove the improperly placed coil.

(Application, page 3, line 14 to page 4, line 6. Emphasis added.)

Accordingly, the present application describes the outer barrier of the present invention as requiring an "external agent" to be applied, before exposing the bioactive agent. In other words, the present invention is more stable (requiring the addition of some

external agent), rather than activating immediately upon insertion into the body (which might be earlier than optimal).

In addition, Appellant's respectfully point out that the principle reference to Wallace does not teach or suggest a bioactive agent disposed on an embolic support member. Thus, it follows that Wallace does not teach or suggest a barrier to prevent a reaction between the bioactive agent and a bodily fluid. This is simply because there is no bioactive agent to protect. Wallace is disclosing a liquid that turns into a solid. See Paragraph #23. Applellant's do not understand what is the embolic support member in Wallace that is to have a bioactive agent disposed thereon and then have a barrier applied to prevent a reaction between the bioactive agent and a bodily fluid? Is it the liquid? Or is it the solid formed from the liquid, which is implanted?

Pinchuk discloses a stent or a catheter that comprises a therapeutic-agent-loaded copolymer that can be covered by a sheath during insertion into the body to prevent premature therapeutic agent release. See Paragraph #183. Pinchuk includes no teaching or suggestion of a bioactive agent and a barrier that is to be dissolved. Thus, for this additional reason, the combination of Wallace and Pinchuk fails to render the present invention obvious.

Conclusion:

For the reasons discussed above, Appellant's maintain that the Examiner's final rejection of claims 17 and 18 under 35 USC § 103(a) should be reversed.

Respectfully submitted,

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Claims Appendix

An appendix containing a copy of the claims involved in the appeal.

Claim 1. (Withdrawn) A medical device comprising:

a support member;

a bioactive agent disposed on said support member; and

an outer barrier disposed on said bioactive agent to prevent exposure of said bioactive agent to bodily fluid when said medical device is inserted into a blood vessel, said outer barrier exhibiting the characteristic of being substantially inert to bodily fluid but dissolving when exposed to an external agent.

Claim 2. (Withdrawn) A medical device as defined in Claim 1, wherein the bioactive agent takes the form of a coating applied to the support member.

Claim 3. (Withdrawn) A medical device as defined in Claim 1, wherein the bioactive agent is integral with the support member.

Claim 4. (Withdrawn) A medical device as defined in Claim 1, wherein the outer barrier takes the form of a coating applied to the bioactive agent.

Claim 5. (Withdrawn) A medical device as defined in Claim 2, wherein the outer barrier takes the form of a coating applied to the bioactive agent.

Claim 6. (Withdrawn) A medical device as defined in Claim 1, wherein said bioactive agent is comprised of polyglycolic acid and said outer barrier is comprised of ethylene vinyl alcohol.

Claim 7. (Withdrawn) A medical device as defined in Claim 6, wherein said external agent is comprised of dimethyl sulfoxide.

Claim 8. (Withdrawn) A medical device as defined in Claim 1, wherein said bioactive agent takes the form of a thrombus inducing coating.

Claim 9. (Withdrawn) A medical device as defined in Claim 2, wherein said bioactive agent takes the form of a thrombus inducing coating.

Claim 10. (Withdrawn) A medical device as defined in Claim 1, wherein said bioactive agent takes the form of a coating which induces the clotting of blood.

Claim 11. (Withdrawn) A medical device as defined in Claim 2, wherein said bioactive agent takes the form of a coating which induces the clotting of blood.

Claim 12. (Withdrawn) A medical device comprising:

a support member;

a bioactive agent disposed on said support member; and,

an outer barrier disposed on said bioactive agent to prevent exposure of said bioactive agent to bodily fluid when said medical device is inserted into a blood vessel, said outer barrier exhibiting the characteristic of being non-water soluble but dissolving when an external activating agent is applied to said outer barrier.

Claim 13. (Withdrawn) A medical device comprising:

a support member;

a bioactive agent disposed on said support member; and,

an outer barrier disposed on said bioactive agent to prevent contact between said bioactive agent and bodily fluid when said medical device is inserted into the body, said outer barrier exhibiting the characteristic of being substantially inert to blood but dissolving and exposing a portion of said bioactive agent when in the presence of a biological agent.

Claim 14. (Withdrawn) A medical device comprising:

a support member;

a bioactive agent disposed on said support member; and,

an outer barrier comprising an activatable agent, said outer barrier covering said bioactive agent and exhibiting the characteristics of substantially preventing a reaction between the bioactive agent and bodily fluid when said medical device is inserted into the body and permitting a reaction between the bioactive agent and bodily fluid upon activation by an external source.

Claim 15. (Withdrawn) A medical device comprising:

a bioactive support member which when placed within the body causes a reaction with bodily tissue; and,

a barrier for preventing a reaction between the bioactive support member and bodily tissue when said medical device is inserted into the body, said barrier exhibiting the characteristic of being non-water soluble but exposing the bioactive support member to bodily tissue when an activating agent is applied to said barrier.

Claim 16. (Withdrawn) A medical device comprising:

a support member which when placed within the body causes a reaction with bodily tissue; and,

a barrier for preventing a reaction between the support member and bodily fluid when said medical device is inserted into the body, said barrier exhibiting the characteristic of exposing a portion of said support member when in the presence of an external agent.

Claim 17. (Previously presented) A method of treatment comprising the steps of:

providing a medical device comprising an embolic support member, a bioactive agent disposed on said support member, and a barrier exhibiting the characteristic of normally preventing a reaction between the bioactive agent and a bodily fluid and of

exposing a portion of said bioactive agent when an external agent is applied to said barrier;

inserting a delivery catheter into a blood vessel;

advancing the distal tip of the delivery catheter through the blood vessel until the distal tip is adjacent to a selected site within the blood vessel;

delivering said medical device with the delivery catheter at the selected site; and,

applying said external agent through the catheter and into the blood vessel to thereby dissolve said barrier to expose said bioactive agent to bodily tissue to thereby cause a reaction between the bioactive agent and the bodily tissue.

Claim 18. (Previously presented) A method of treatment comprising the steps of:

providing a medical device comprising an embolic support member having a bioactive surface which reacts with bodily tissue, and having a barrier which exhibits the characteristic of normally inhibiting a reaction between said bioactive surface of said medical device and bodily tissue;

inserting a delivery catheter into a blood vessel;

advancing the distal tip of the delivery catheter through the blood vessel until the distal tip is adjacent a selected site within the blood vessel;

delivering said medical device with the delivery catheter at the selected site; and,

applying said external agent through the catheter to a selected site to thereby dissolve said barrier and thus expose said bioactive surface to bodily tissue to thereby cause a reaction between the bioactive surface and the bodily tissue.

Evidence Appendix

No evidence has been submitted by Appellant pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 during the prosecution of this application. Nor has any other evidence been entered by the Examiner and relied upon by Appellant in the appeal.

Related Proceedings Appendix

Pursuant to 37 C.F.R. 41.37(c)(1)(ii), Appellant, the Appellant's legal representative, or the Assignee is not aware of any decisions that have been rendered by a court or the Board in any proceeding that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.